

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.*
JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

SUBMISSION REGARDING DEFENDANT’S PROPOSED CASE SCHEDULE

Pursuant to the Court’s March 13, 2024 Order, Defendant Janssen Biotech, Inc. (“Janssen”) respectfully asks that the Court enter an order setting a case schedule consistent with the schedule identified below. Janssen’s proposed schedule is straightforward, efficient, and fair, and it comports with standard litigation practice and the Court’s desire to test Relator’s Phase One claims. Relator’s proposed schedule is none of those things.

I. Background

At the March 13, 2024 status conference, following agreement of the parties, the Court set the Phase One party discovery cut-off as September 30, 2024, and increased the number of fact depositions Relator may take to twenty. The Court then asked the parties to submit proposals on the process and timing for expert discovery, summary judgment, and trial.

On March 21, 2024, the parties engaged in a meet and confer to discuss an appropriate case schedule. The discussion focused on identifying a process that is reasonable and efficient in light of the present uncertainty regarding the causation standard applicable to Relator’s claims. Janssen expressed its view that, in order for the case to proceed as expeditiously as possible, the parties should conduct all Phase One discovery now—including third-party causation

discovery—on the assumption that the First Circuit will affirm the but-for causation standard identified by this Court in the *Regeneron* case. *See* Mem. & Order, *United States v. Regeneron Pharms., Inc.*, No. 20-11217-FDS (D. Mass. Sept. 27, 2023), ECF No. 351. In Janssen’s view, while it is possible such an approach could lead to some inefficiency should the First Circuit determine that Relator’s claims are subject to a more lenient causation standard, Relator will require *some* evidence of causation under any causation standard. There is a risk that Relator might end up pursuing more evidence of causation than may ultimately be required to support her claims. At this stage, however, it is impossible to know whether this approach would result in any inefficiency: it may or it may not. Any potential for inefficiency should be balanced against the desire to advance the case in an orderly fashion under the present circumstances.

Not surprisingly, Relator informed Janssen that she would object to conducting third-party causation discovery until after the First Circuit decides the applicable causation standard. In an attempt to accommodate Relator’s position, Janssen proposed a schedule, which is identified and discussed below. That schedule provides for third-party causation discovery to be conducted only after the First Circuit identifies the applicable causation standard, followed by reasonable deadlines for the case through expert discovery, summary judgment, and trial.

Relator rejected Janssen’s proposal. Instead, Relator proposed a peculiar and contorted schedule that would prejudice Janssen and benefit Relator. The schedule proposed by Relator, which is attached as Exhibit A, does not comport with the process the Court described during the status conference, and it deviates significantly from standard litigation practice and this Court’s own scheduling practices in similar cases. Furthermore, it would lead to an inefficient and wasteful litigation process, with no trial until at least 2026.

II. Relator's Proposed Schedule

For a variety of reasons, Relator's proposed schedule is inefficient, unfair, and inconsistent with the Court's instruction that Relator's "Phase One" claims (relating to the region for which she was responsible and has direct knowledge) should be tested before the parties proceed with Phase Two discovery.

First, although Relator bears the burden of proof, under Relator's proposed schedule, Defendant would be required to disclose expert opinions before experts are designated by Relator—even as Relator reserves the right to rely affirmatively on whatever expert opinions she chooses regardless of whether Defendant relies on any expert opinions at all.

Second, Janssen would be required to file its motion for summary judgment before Relator has disclosed anything about the expert opinions she will rely upon in opposing that motion. This backwards process would inevitably require Janssen to refile the summary judgment motion to address Relator's subsequently-disclosed expert opinions, which is presumably why courts—including this Court—do not typically follow such an approach.

Third, Janssen would be forced to file an incomplete motion for summary judgment that does not address causation. This would likely insulate Relator's Phase One claims from any causation challenge in Janssen's initial summary judgment motion on an issue so critical that this Court and another in this district¹ certified the question for interlocutory appeal and stayed those pending False Claims Act cases until it is resolved. Then, regardless of how the First Circuit decides the issue, causation would need to be addressed through additional summary judgment briefing and, likely, additional third-party and expert discovery. It is inefficient to address

¹ *United States v. Teva Pharmaceuticals USA, Inc.*, No. 20-11548-NMG (D. Mass.).

discovery and summary judgment in such a piecemeal way, with multiple rounds of motions and, perhaps, multiple rulings.

Fourth, Relator proposes that if her claims survive summary judgment, the parties would proceed immediately to Phase Two. According to Relator, this should occur even if the issue of causation has not yet been tested in any way. This is inconsistent with the entire concept of testing Relator's case before proceeding with discovery regarding Janssen's activities in other territories around the country. The outcome of full Phase One summary judgment (including causation) may be dispositive of the entire case and render additional discovery unnecessary. If it is not, it will allow the Court and the parties to make fully informed decisions about what has already been decided and what should occur next.

At bottom, Relator's proposed schedule is overly complicated and inefficient, to the detriment of Janssen. As indicated in Exhibit A, Relator has proposed 17 events to take place between the September 30, 2024 cut-off for party discovery and the conclusion of briefing on dispositive motions, including repeated sur-replies to anticipated Janssen motions to ensure Relator never has to file first, but always gets the last word. More importantly, Relator's proposed schedule does nothing to promote the speedy resolution of this litigation; to the contrary, it would ensure that no trial could possibly occur until at least 2026,² while creating the risk that additional, duplicative proceedings would be required depending on the timing of the First Circuit's causation ruling.

² Relator's proposal would not result in a trial date before 2026 even in the unlikely event that (i) the First Circuit rules on the causation standard by September 30, 2024, (ii) Relator completes third-party causation discovery within 60 days thereafter, and (iii) the Court issues a summary judgment decision just 24 hours after briefing on that motion is completed.

By contrast, Janssen's proposal, described below, would not prejudice either party and would preserve resources. Under Janssen's proposal, to the extent the First Circuit has not yet ruled by September 30, 2024, further activity would be deferred for a short time until the First Circuit has ruled. Then, the case would move forward in an orderly, prompt fashion with the parties fully informed on the law.

III. Janssen's Proposed Schedule

Janssen believes that adhering to a traditional schedule for discovery and dispositive motions is the most fair and efficient way to proceed in this litigation. Thus, Janssen proposes a process and schedule similar to the one implemented in another case over which this Court is presiding: *United States v. Regeneron Pharms., Inc.*, No. 20-11217-FDS (D. Mass.).

Janssen would be comfortable with the Court's suggestion of a Spring 2025 trial if Relator would be willing to complete all fact discovery (including third-party causation discovery) by September 30, 2024. However, given Relator's objection to proceeding with third-party causation discovery until after the First Circuit's decision regarding the applicable causation standard, Janssen proposes the following schedule:

<u>Janssen's Proposed Case Schedule</u>	
Event	Proposed Deadline
All fact discovery, including depositions, other than third-party causation discovery, must be completed by:	September 30, 2024
Third-party causation discovery must be completed by:	60 days after September 30, 2024 or First Circuit ruling in <i>Teva</i> or <i>Regeneron</i> appeal, whichever occurs later
Relator's trial experts must be designated, and the information contemplated by Fed. R. Civ. P. 26(a)(2) must be disclosed, by:	15 days after close of third-party causation discovery
Relator's trial experts must be deposed by:	45 days after designation of Relator's experts

Defendant's trial experts must be designated, and the information contemplated by Fed. R. Civ. P. 26(a)(2) must be disclosed, by:	15 days after deposition of Relator's experts
Close of expert discovery / Defendant's trial experts must be deposed by:	45 days after designation of Defendant's experts
Dispositive motions must be filed by:	30 days after close of expert discovery
Oppositions to dispositive motions must be filed by:	30 days after filing of dispositive motions
Reply briefs in support of dispositive motions must be filed by:	15 days after filing of opposition to dispositive motion
Final Pretrial Conference	To be determined by the Court
Trial	To be determined by the Court

Janssen's proposed schedule accommodates Relator's desire to postpone third-party causation discovery, as well as expert discovery and summary judgment briefing on causation, while allowing the case to proceed in an expeditious, efficient, and orderly manner once the causation standard is established by the First Circuit. This would accommodate the Court's long-stated goal of testing Relator's claims on all issues.

By contrast, as discussed above, Relator's proposed schedule uses Relator's desire to defer third-party causation discovery as an excuse to justify a highly unusual and self-serving case schedule that is prejudicial to Janssen, inefficient, and wasteful, all while ensuring that no trial could take place until at least 2026.

IV. Conclusion

For the foregoing reasons, Janssen requests that the Court enter an order setting the case schedule that Janssen proposes above.

Dated: April 10, 2024

Respectfully Submitted,

/s/ Jason C. Raofield

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 10th day of April, 2024.

/s/ Jason C. Raofield

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